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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,580	11/21/2003	Frederic Beseme	105045.01	3397

25944 7590 08/30/2007

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER	
MITCHELL, LAURA MCGILLEM	
ART UNIT	**PAPER NUMBER**
1636	

MAIL DATE	DELIVERY MODE
08/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,580	BESEME ET AL.	
	Examiner	Art Unit	
	Laura M. Mitchell	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,10,20-23,30 and 36-39* is/are pending in the application.

4a) Of the above claim(s) *21-23,30 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 5-6, 10, 20 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/446,024.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 3-4, 7-9, 11-19, 24-29, 31-35 are cancelled, claim 10 has been amended, claims 21-23, 30 and 36 are withdrawn and claim 39 has been added in the response filed 2/22/2007. Claims 1-2, 5-6, 10, 20 and 37-39 are under examination.

Election/Restrictions

Applicant's election with traverse of SEQ ID NO:25 as a species for claim 39 in the reply filed on 6/11/2007 is acknowledged. The traversal is on the ground(s) that claim 39 reads on the elected species.Applicants submit that it is generic to all species.

Applicants submit that the subject matter of all species is sufficiently related that a thorough search for the subject matter of any one species would encompass a search for the subject matter of the remaining species. Applicants submit that the search and examination of the entire application could be made without serious burden. See MPEP §803 in which it is stated that "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions". Applicants submit that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

This is not found persuasive. Applicant's attention is directed to the Notice published in the Official Gazette (1316 OG 122) which as of February 22, 2007 supersedes MPEP 803.04. The announcement states in part:

> "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up

> to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications.
>
> For National applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superceded by this Notice). Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.
>
> For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art."

Each of SEQ ID NOs:16-28 is structurally, functionally and biochemically distinct from one another. Therefore the sequences of SEQ ID NOs:16-28 are independent. A search for one of the sequences would not encompass a search for any of the other sequences and would therefore constitute a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

It is noted that Applicant has submitted two non-patent literature references with response filed 2/22/2007. These documents have not been listed in a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office. However, the references have been considered by the examiner and made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8-9 and 13-17 are cancelled, rendering the rejection moot as to those claims.

Claim 10 has been amended to remove the word "derived". The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite regarding the word "derived" has been withdrawn.

Claim 10 stands rejected as vague and indefinite because it recites the phrase "highly stringent" conditions and the metes and bounds of highly stringent hybridization conditions are not clear.

This rejection is being maintained for reasons of record in the previous Office Action, mailed 8/24/2006 and for reasons outlined below.

Applicants disagree that the term highly stringent conditions is vague and indefinite, because the term "high" is a subjective term with subjective scope. Applicant submits that because "highly stringent" conditions are well known and recognized in the art, the term would not be considered by one of ordinary skill in the art to be a subjective term, and thus would not be deemed indefinite. For example, the attached excerpt from George H.Keller et al., DNA Probes, 2d Ed., pp. 5-10 (1993), demonstrates that "highly stringent" conditions are well known and recognized in the art.

Applicant submits that this reference demonstrates that one of ordinary skill in the art could readily determine highly stringent conditions based on the knowledge he possesses. Applicant submits that at least these reasons, the term "highly stringent" conditions is not indefinite, and its scope would be readily apparent to and recognized by one of ordinary skill in the art.

Applicant's arguments filed 2/22/2007 have been fully considered but they are not persuasive. The Keller et al reference discusses stringency at pages 8-10. Keller et al teach that the factors that affect stability of hybrids determine stringency of the hybridization conditions. Keller et al disclose that hybridization occur most readily at a temperature that is 25°C below the T_m of the hybrids and teach calculation of T_m. Keller et al discuss use of formamide when using RNA to keep the hybridization temperature low. Keller et al disclose that when performing filter hybridizations with long probes, the most stringent conditions are applied during final washes of the filter and teach "typical" final wash conditions. Keller et al does not define or exemplify specific low or high stringency conditions. Keller et al do teach that optimum hybridization temperature for oligonucleotides must be empirically determined. However, this rejection is not one of lack of enablement (how to make or use), but for being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

One of skilled in the art would not know the metes and bounds of highly stringent conditions as Applicants intend. Since hybridization conditions should be empirically determined, the skilled artisan would not know what conditions would meet the

limitations of "highly stringent" as claimed by the Applicants. The word "highly" is a relative term. "When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree" See MPEP 2173.05(b). Without some disclosed or claimed standard level of stringency as intended by the Applicants, the skilled artisan would not know metes and bounds of whether hybridization condition would constitute "highly stringent conditions" and meet the limitations of the claimed method.

Applicant's arguments, see REMARKS, filed 2/22/2007, with respect to the term "retroviral RNA molecule" have been fully considered and are persuasive. The rejection of claims 1-2, 5-6, 20 and 37-38 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-6, 10, 20 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW Rejection.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

Claim 1 is drawn to a molecule that encompasses sequences that exhibit for every sequence of 100 contiguous monomers at least 70% homology with SEQ ID NO:11. Claim 37 is drawn to a molecule that encompasses sequences that exhibit for every sequence of 100 contiguous monomers at least 80% homology with SEQ ID NO:11. Claim 38 is drawn to a molecule that encompasses sequences that exhibit for every sequence of 100 contiguous monomers at least 90% homology with SEQ ID NO:11. SEQ ID NO:11 is 7582 base pairs in length.

The claim encompasses sequences of as little as 100 contiguous nucleotides that can be 70%, 71%, 73%, 75%, 80%, 85%, 90%, 95%, etc. homologous to SEQ ID NO:11. Given the length of SEQ ID NO:11, it comprises an extremely high number of at least 100 contiguous nucleotides with homology to SEQ ID NO:11. The instant specification does not disclose or contemplate even a few of sequences with the limitation of every sequence of 100 contiguous monomers at least 70% homology with SEQ ID NO:11.

Claim 2 is drawn to a molecule that encompasses sequences encoding any peptide exhibiting for every sequence of at least 30 amino acids at least 80% identity

with a peptide sequence encoding by at least a functional part of SEQ ID NO:11. This encompasses an extremely large group of sequences. The specification does not sufficiently disclose a "functional part" of SEQ ID NO:11 beyond the portions that have identity to known retroviral proteins. The claim encompasses sequences of as little as 30 amino acids that can have 80%, 81%, 83%, 85%, 90%, 95%, etc. identity to a peptide sequence encoded by at least a functional part of SEQ ID NO:11. Given the length of SEQ ID NO:11, it comprises a sequence that encodes an extremely high number of 30 contiguous amino acid sequences encoded by SEQ ID NO:11. The instant specification does not disclose or contemplate even a few of sequences with the limitation of sequence that encodes an extremely high number of 30 contiguous amino acid sequences encoded by SEQ ID NO:11.

The specification discloses that SEQ ID NO:11 is a reconstructed putative genomic RNA from smaller clones detected by screening a cDNA library with Ppol-MSRV probes (see Figure 1). The specification discloses that the reconstructed sequence has the structure of R-U5-gag-pol-env-U3-R and that the sequences are found on several chromosomes (see paragraph 0002). The instant disclosure states that the reconstructed sequence is integrally contained in a genomic clone RG083M05. Applicants have aligned the reconstructed sequence with the genomic clone and found that it exhibits 96% similarity with two discontinuous regions of RG083M05. From this alignment, the Applicants have deduced an LTR sequence and identified elements characteristic of retroviruses. Applicants have called this sequence HERV-W.

The specification discloses that the HERV-W is expressed in placenta, but merely speculates about the function in placenta. Applicants suggest that expression of the HERV-W in the placenta may be under the control of isolated LTR and may result in pathology from aberrant expression. Applicants speculate on a fusogenic role at the level of cellular subtypes in the placenta, an immunosuppressive role and a protective role (see paragraph 0008-0010). Applicants propose that a verification of these implications may lead to establishment of diagnostic methods. The specification suggests that the sequence can be a molecular marker for an autoimmune disorder, or a molecular marker for a pathology that is associated with a pathological pregnancy, or a chromosomal marker for susceptibility to an autoimmune disease. Further, applicants disclose that a nucleotide fragment would be useful as a diagnostic composition, such as in diagnostic hybridization techniques (see paragraph 0078). Therefore, there is no concrete function established for the sequence of SEQ ID NO:11 other than encoding retrovirus elements.

The specification discloses one sequence of SEQ ID NO:11 as well as shorter sequences that were used to deduce the sequence of SEQ ID NO:11 for the claimed sequences that exhibit homology to SEQ ID NO:11. There is no description of how the structure of the putative genomic RNA sequence identified as SEQ ID NO:11 relates to the proposed functions. Beyond expression in the placenta, and identity to gene encoding retroviral env, pol and gag sequences, the specification has not described characteristics or specific regions of SEQ ID NO:11 that would provide a correlation between structure and function. There is no description of how a sequence that exhibits

for every sequence of 100 contiguous nucleotides at least 70% identity with SEQ ID NO:11 is representative of sequences with the proposed functions. There is no description of how a sequence that encodes one of an extremely high number of 30 contiguous amino acid sequences encoded by SEQ ID NO:11 is representative of sequences with the proposed functions.

The common attributes of the SEQ ID NO:11 sequence linked to function are not described and the identifying attributes of the individual sequences that exhibit for every sequence of 100 contiguous nucleotides at least 70% identity with SEQ ID NO:11 to the disclosed sequence are not described. Therefore, there is not a structural and functional basis provided by the prior art or the specification for one of ordinary skill in the art to envision all sequences that exhibits for every sequence of 100 contiguous nucleotides at least 70%, at least 80% identity or at least 90% with SEQ ID NO:11 that would be markers for autoimmune disorders or pathological pregnancy, or useful for diagnostic compositions.

Claim 10 is drawn to a primer for amplification of the molecule according to claim 1 comprising a sequence that hybridizes to the nucleotide sequence of the molecule according to claim 1. Claim 39 is drawn to a probe for detection of the molecule according to claim 1, wherein the probe is selected forma group of sequences. However, since claim 1 encompasses an enormous number of sequence that are at least 70% homologous to SEQ ID NO:11, there is at least an equally large genus of primers and probes that would hybridize to this large number of sequences. The instant specification has not described or exemplified this large genus of primers or probes.

Claim 20 is drawn to a diagnostic composition comprising the molecule according to claim 1. As above, molecule of claim 1 comprising a very large genus of sequences of varying homology to SEQ ID NO:11. A structural/ function correlation for SEQ ID NO:11 and the claimed homologous sequences has not been established in the description of the invention. Therefore, there is no correlation between structure of the sequence of SEQ ID NO:11 and the claimed homologous sequences and its claimed function as a diagnostic composition. According to these facts, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variant of the genus and is insufficient to support them.

Claims 1-2, 5-6, 10, 20 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a NEW rejection.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation *United States v. Telectronics*, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

1) Scope of the claims. The claimed molecule encompasses an enormous number of genomic RNA molecules, probe and primers.

2) State of the Art. Near the time the invention was made, Urnovitz and Murphy reviewed human endogenous retroviruses (HERV) (Clinical Microbiology Reviews, 1996, Vol. 9, No. pages 72-99). Urnovitz and Murphy teach that HERV proteins are expressed *in vivo* and cause detectable immunologic responses to putative HERV-encoded antigens (see page 86, right column, for example). Urnovitz and Murphy teach that placental HERV products may be expressed as antigens. Urnovitz and Murphy also teach that there may be a correlation between antibodies specific for virus protein p30 in umbilical cord blood serum and complications during pregnancy (see page 87, left column, 1st paragraph, for example). Antigens that are related to the p30 protein in teratocarcinomas have been documented, however Urnovitz and Murphy teach that it is uncertain whether members of the HERV family encode these p30 like antigens. Urnovitz and Murphy caution that whether such antigens elicit autoimmune activity warrants careful documentation (see page 87, right column). There appears to be no disclosed correlation between endogenous retroviral sequences known in the prior art and the instantly claimed molecule with regard to specific disease or disorders.

3) Unpredictability of the art. It is unpredictable whether a composition comprising the sequence of SEQ ID NO:11 or every sequence of 100 contiguous monomers at least 70% homology, at least 80% homology or at least 90% homology with SEQ ID NO:11 would be functional as a diagnostic composition or a marker for autoimmune disease or pathologic pregnancy because there has been no significant

correlation with the claimed sequences and these conditions. Although claimed sequence has been found to be expressed in placenta, the specification does not specify whether the sequences can be found in pathologic placenta or in tissue affected by autoimmune disorders. If so the specification has not sufficiently demonstrated a correlation between the claimed sequences and the disclosed disorders that would suggest that the claimed sequence would be useful as diagnostic markers.

4) Amount of guidance provided. Although the specification discloses that the sequences comprised within the proposed HERV-W sequence are expressed in the placenta and speculates that the claimed nucleic acid molecules can be used to diagnose risk of a pathological pregnancy or risk of unsuccessful pregnancy based, there is no sufficient disclosure presented in the specification as to why the recited sequences should be associated with a pathological pregnancy. For example, there is no comparison of expression of the nucleic acids of the invention in abnormal pregnancies to expression of the same sequences in normal pregnancies. The specification does not provide sufficient information so that the skilled artisan would know how to make or use the claimed molecules in a diagnostic composition. The Applicants have not provided sufficient description or guidance that would correlate the sequences, probes, primers with a particular disease or condition, such as autoimmune disease or pathological pregnancy, that it is predicted to be associated. There is no guidance on how to make or use a functional diagnostic composition for a specific disorder.

5) Working examples. The specification does not disclose, exemplify or contemplate any alteration in expression of the claimed molecules in pathologic tissue. The specification does not present any working example of the claimed molecules as diagnostic compositions or disclose specific examples of how to use the diagnostic composition.

6) Nature of the invention. The invention encompasses nucleic acid sequences obtainable from tissue and with homology to genes encoding retroviral RNA, as well as primers and probes for amplifying and detection of the sequence. The invention encompasses diagnostic compositions comprising the claimed molecules.

7) Level of skill in the art. The skill in the art is high, but given the scope and nature of the invention, state and unpredictability of the art, lack of guidance and working example, the skilled artisan would have to employ excessive and undue trial and error experimentation in order to make the claimed molecules and compositions.

Given the above analysis of the factors which the Courts have determined are critical in ascertaining whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have practiced undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 102

Claims 8, 13 and 15-17 have been canceled, therefore the rejection of claims 8, 13 and 15-17 under 35 U.S.C. 102(a) as being anticipated by NCBI report of Human BAC clone RG083M05 from chromosome 7q21-7q22 by Pauley is moot.

It is noted that Applicants point out that the Office Action has not established that the NCBI report in fact qualifies as prior art to the present claims. Applicant submits that although the reference indicates that it was "submitted" November 13, 1996, the Office Action has not indicated when the reference was actually published, and thus available as prior art. To address the concern of the Applicant, the submission date is being used as the date the information was available to the public, or a data that the invention was "known or used by others in this country".

Claims 8, 13 and 15-17 have been canceled, therefore the rejection of claims 8, 13 and 15-17 under 35 U.S.C. 102(b) as being anticipated by Jurka et al (J. Mol. Evol. 1992, Vol. 35, No. 4, pages 286-291) is moot.

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (U.S. Patent No. 5,708,157, filed 7/26/1996). Claims 8-9, 13 and 15-17 have been canceled, therefore the rejection of claims 8-9, 13 and 15-17 under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (U.S. Patent No. 5,708,157) is moot.

This rejection is being maintained for reasons of record in the previous Office Action, mailed 8/24/2006 and for reasons outlined below.

Applicant submits that with respect to the rejection over Jacobs, the rejection includes claim 10, but because claim 10 depends from claim 1, which has not been rejected, the rejection of claim 10 over Jacobs is improper.

Applicant's arguments filed 2/22/2007 have been fully considered but they are not persuasive. Claim 10 is drawn to a primer comprising a nucleotide sequence that hybridizes under highly stringent conditions with the nucleotide sequence of the molecule of claim 1 or with any specific amplification product thereof. Claim 1 recites that the claimed molecule is "selected from the group consisting of SEQ ID NO:11 and sequences that exhibit at least 70% homology with SEQ ID NO:11 for every sequence of 100 contiguous monomers". Therefore one of the choices in the group is SEQ ID NO:11, which is 7582 base pairs in length. Claim 10 does not require that the primer be able to hybridize with the entire sequence of SEQ ID NO:11. Since the specification defines primer as "a probe comprising at least six monomers, and advantageously from 10 to 30 monomers, possessing a hybridization specificity under determined conditions" (see paragraph 0080), it does not appear that Applicants intend a primer to be 7582 base pairs in length. Therefore in order to meet the limitations of claim 10 a primer must only hybridize to a portion of the sequence of the molecule according to claim 1. Therefore, Jacobs et al does not have to anticipate claim 1 in order to anticipate the primer of claim 10.

Jacobs et al teach a double stranded polynucleotide sequence known as SEQ ID NO:48 (see column 15, lines 65-67 and column 16, lines 1-10, for example). Jacobs et al teach that the sequences can incorporate labels or markers for various uses including use as probes and primers (see column 29, lines 30-60, for example). A portion of SEQ ID NO:48 from nucleotide 152 to nucleotide 341 displays a 100% local similarity to nucleotide 5390 to nucleotide 5579 of disclosed instant SEQ ID NO:11. Within that

sequence, for example, the first six nucleotide sequences (nucleotide 152 to nucleotide 158) would anticipate a probe containing at least six monomers.

Although the claim recites the phrase "for amplification of the molecule according to claim 1", this is a preamble phrase which is drawn to the function of the claimed product. Absent evidence to the contrary, a probe comprising at least six monomers from SEQ ID NO:48 as taught by Jacobs et al would hybridize under highly stringent conditions with said SEQ ID NO:11 nucleotide sequence or any specific amplification thereof and would be functional for amplification of the molecule according to claim 1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem Mitchell, PhD
Examiner
8/23/2007

CELINE QIAN, PH.D.
PRIMARY EXAMINER